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(54) METHODS OF MANUFACTURE OF RADIALLY-ENLARGEABLE PTFE TAPE-REINFORCED VASCULAR GRAFTS

VERFAHREN ZUR HERSTELLUNG VON RADIAL EXPANDIERBAREN, BANDVERSTÄRKTEN POLYTETRAFLUORÄTHYLENGEFÄSSTRANSPLANTATEN

PROCEDES DE FABRICATION DES GREFFES VASCULAIRES EN PTFE, EXTENSIBLES RADIALEMENT ET RENFORCEES PAR BANDE

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Field of the Inventi n

[0001] The present invention relates generally to bioprosthetic vascular grafts, and more particularly to a method of manufacturing radially enlargeable, tubular, tape-reinforced polytetrafluoroethylene (PTFE) vascular grafts.

Background of the Invention

[0002] Polytetrafluoroethylene (PTFE) has been used for the manufacture of various types of bioprosthetic vascular grafts, including tape-reinforced, tubular grafts of the type frequently utilized to replace or bypass a diseased or injured segment of blood vessel.

[0003] The expanded sintered PTFE from which the tubular base graft and the surrounding reinforcement tape are formed typically has a microstructure characterized by the presence of dense areas known as "nodes" interconnected by elongate strands known as "fibrils". The directional orientation of fibrils is largely determined by the direction(s) in which the material was expanded prior to sintering thereof. The diameter and spacing of the fibrils is largely determined by the dynamics (i.e., rate frequency and amount) of the expansion. The porosity of the expanded sintered PTFE material is determined by the size of the spaces which exist between the fibrils, after the expansion step has been completed.

[0004] The sintering of the expanded PTFE is accomplished by heating the expanded workpiece to a temperature above the melting point of crystalline PTFE. Typically, this is effected by heating the workpiece to a temperature of 350-370°c. This sintering process is characterized by a transition of the PTFE polymer from a highly crystalline form to a more amorphus form. Thus, the sintering process is sometimes referred to as "amorphous locking" of the PTFE polymer. The sintering process imparts significantly improved strength to the PTFE polymer matrix, while also causing the polymer matrix to become harder and less stretchable.

[0005] In the tape-reinforced PTFE vascular grafts of the prior art, it has been typical for the PTFE reinforcement tape to be wound spirally about the outer surface of the base graft. Such orientation and positioning of the relatively thin, sintered, PTFE reinforcement tape about the outer surface of the base graft substantially precludes or severely limits the amount of radial stretching or radial expansion that the base graft may undergo. Thus, the typical tape-reinforced tubular PTFE vascular graft of the prior art is incapable of undergoing more than a minimal amount (e.g., <5%) of radial stretching or radial expansion without tearing of the surrounding reinforcement tape.

[0006] The inability of tape-reinforced PTFE vascular grafts to undergo radial stretching or radial expansion has not interfered with the usual surgical implantation of such grafts because, in the usual surgical graft implantation procedure, the graft is sized-matched to the host blood vessel and is subsequently anastomosed into or onto the host blood vessel. Thus, in traditional surgical implantation procedures, there has been little or no need to effect radial stretching or radial expansion of the graft at the time of implantation.

[0007] Recently developed endovascular grafting procedures have, however, created a need for tape-reinforced tubular PTFE vascular grafts which are capable of undergoing significant amounts of radial enlargement (i.e., radial expansion with resultant enlargement of the radial dimension of the graft). In these endovascular grafting procedures, the tubular vascular graft is typically passed through a catheter into the lumen of a deceased blood vessel and, thereafter, is deployed to an open or extended configuration within the lumen of the host blood vessel. The graft is then anchored to the surrounding blood vessel wall, thereby effecting the desired endovascular placement of the graft within the lumen of the existing blood vessel. Thus, because it is necessary to initially compact the graft and pass it through the lumen of a relatively small catheter, and to subsequently radially enlarge the graft to its desired size and configuration, there exists a present need for the development of a tape-reinforced tubular vascular graft which is capable of undergoing *in situ* radial enlargement within the lumen of an existing blood vessel.

[0008] WO-A-95/05132 discloses an intraluminal stent comprising a tubular base graft, which can be diametrically expanded and is covered with porous, expanded PTFE film.

[0009] US-A-5122154 discloses an endovascular bypass graft comprising a plurality of diametrically expandable stents covered with expanded PTFE.

[0010] EP-A-0232543 discloses that a known stent comprises a PTFE tube, reinforced with a PTFE tape wound around the outer surface of the tube, integrating the two layers. This document discloses that the tape may be avoided by using a sintered PTFE tube, oriented in both the axial and circumferential directions.

[0011] The features of the present invention are set out in Claim 1 which requires a method for manufacturing a radially enlargeable tape-reinforced tubular vascular graft, said method comprising the steps of:

a) providing a workpiece comprising:

(i) a tubular base graft having an outer surface and a hollow lumen extending longitudinally therethrough, said tubular bas graft being formed substantially of a sintered fluoropolymer material, and
(ii) reinforcement tape wound about the outer surface of said tubular base graft, said r inforcement tape comprising a film formed substantially of sintered fluoropolymer material, and

b) radially shrinking said workpiece, thereby causing the graft to assume a radially shrunken state from which said graft may be subsequently radially enlarged.

[0012] The present invention comprises a method for increasing or improving the ability of a tape-reinforced tubular graft to undergo radial enlargement without tearing or breaking.

[0013] A radially enlargeable tape-reinforced tubular vascular graft is formed by initially manufacturing the tape-reinforced graft in accordance with any suitable manufacturing methodology, and subsequently radially shrinking the tape-reinforced graft to a decreased radial size. Such radial shrinkage of the tape-reinforced graft may be accomplished gradually, or in incremental steps, to minimize the likelihood of puckering of the tubular base graft as the surrounding reinforcement tape shrinks. Also, such radial shrinkage of the graft may be accomplished by any suitable polymer shrinkage technique, including heat-induced shrinkage or chemical-induced shrinkage.

[0014] One or more rigid mandrel(s) may be inserted into the lumen of the tubular base graft during the shrinkage process. In embodiments of the invention wherein the shrinkage process is accomplished in incremental or step wise manner, a single mandrel of adjustable diameter, or multiple mandrels of incrementally smaller diameter, may be utilized to effect the desired gradual, incremental or step-wise shrinkage of the graft.

[0015] The desired shrinkage of the tape-reinforced graft may be accomplished by passing the tape-reinforced graft through a sizing dye to accomplish the desired radial shrinkage thereof.

[0016] The radially enlargeable tape-reinforced PTFE vascular graft may be alternatively formed by initially wrapping the expanded sintered PTFE reinforcement tape about the rigid mandrel to create a tape-tube which is devoid of any tubular base graft. The tape-tube is then radially shrunken, in accordance with the present invention, and the radially shrunken tape tube is subsequently applied to the outer surface of a relatively small-diameter tubular base graft. The tubular base graft and the surrounding shrunken tape-reinforcement may then be radially enlarged in accordance with the present invention, without tearing or breaking of the reinforcement tape.

[0017] Any embodiment of the radially enlargeable tape-reinforced tubular PTFE grafts of the present invention may be provided with external support filaments or beading to provide structural support to the graft, and to prevent indentation or kinking of the graft lumen when implanted. Such support filaments or beading may be formed of PTFE or any other suitable material.

[0018] Further objects and advantages of the invention will become apparent to those skilled in the art upon reading and understanding of the following detailed description, and consideration of the accompanying figures.

Brief Description of the Drawings

[0019]

Figure 1 is a block diagram showing a presently preferred method for manufacturing a radially enlargeable, tape-reinforced, tubular vascular graft of the present invention.
Figure 2 is block diagram showing an alternative method for manufacturing a radially enlargeable tape-reinforced tubular vascular graft of the present invention.
Figure 3 is a block diagram showing a presently preferred method for endovascular implantation and *in situ* radial expansion of a tape-reinforced vascular graft of the present invention.

Detailed Description of the Preferred Embodiment

[0020] The following detailed description and the accompanying drawings to which it refers are provided for purposes of describing and illustrating the presently preferred embodiments of the invention, and are not intended to limit the scope of the invention in any way.

1. Method for Manufacturing a Radially Expandable Tape-Reinforced, PTFE Vascular Graft

[0021] As shown in the block diagram of Figure 1, the preferred method of manufacturing a tape-reinforced vascular graft of the present invention involves separate preparation of a) an expanded, sintered, tubular PTFE base graft and b) an expanded, sintered PTFE reinforcement tape. The PTFE reinforcement tape is then spirally wound about and laminated or fused to the outer surface of the tubular base graft, thereby forming the desired tape-reinforced vascular

graft.

[0022] Thereafter, in accordance with the present invention, the sintered, tape-reinforced, tubular vascular graft is radially shrunken to a reduced radial dimension, such that the graft may be subsequently stretched or expanded to or near its original (pre-shrinkage) radial dimension.

A. Preparation of the Tubular Base Graft

[0023] The preferred method for preparing the expanded, sintered PTFE tubular base graft is shown in Figure 1.

i.) Preparation of Paste

[0024] The manufacture of the tubular base graft begins with the step of preparing a PTFE paste dispersion 10 for subsequent extrusion. This PTFE paste dispersion may be prepared by known methodology whereby a fine, virgin PTFE powder (e.g., F-104 or F-103 Virgin PTFE Fine Powder, Dakin America, 20 Olympic Drive, Orangebury, NY 10962) is blended with a liquid lubricant, such as odorless mineral spirits (e.g., Isopar®, Exxon Chemical Company, Houston, TX 77253-3272), to form a PTFE paste of the desired consistency.

ii.) Extrusion of Tube

[0025] The PTFE-lubricant blend dispersion is subsequently passed through a tubular extrusion dye to form a tubular extrudate 12. The extrudate formed in this step of the method has a diameter or cross-dimension which is approximately the same as the final diameter or cross-dimension desired of the graft after it has been implanted and subjected to in-situ radial expansion in accordance with the present invention.

iii.) Drying

[0026] The wet tubular extrudate is then subjected to a drying step 14 whereby the liquid lubricant is removed. This drying step 14 may be accomplished at room temperature or by placing the wet tubular extrudate in an oven maintained at an elevated temperature at or near the lubricants dry point for a sufficient period of time to result in evaporation of substantially all of the liquid lubricant.

iv.) Expansion

[0027] Thereafter, the dried tubular extrudate is longitudinally expanded 16 or longitudinally drawn at a temperature less than 327°c and typically in the range of 250-326°c. This longitudinal expansion 16 of the extrudate may be accomplished through the use of known methodology, and may be implemented by the use of a device known as a batch expander. Typically, the tubular extrudate is longitudinally expanded by an expansion ratio of more than two to one (2:1) (i.e., at least two (2) times its original length).

v.) Sintering

[0028] After the longitudinal expansion step has been completed, the tubular extrudate is subjected to a sintering step 18 whereby the extrudate is heated to a temperature above the sintering temperature of PTFE (i.e., 350-370°c) to effect amorphous-locking of the PTFE polymer. The methodology used to effect the sintering step, and the devices used to implement such methodology, are known in the art.

[0029] Completion of the sintering step 18, marks the completion of the preparation of the expanded, sintered PTFE base graft.

B. Preparation of Reinforcement Tape

i.) Preparation of Paste Dispersion

[0030] In accordance with preferred method shown in Figure 1, the preparation of the expanded sintered PTFE reinforcement tape includes the initial preparation of a PTFE paste dispersion 20. The PTFE paste dispersion prepared in this step 20 may be prepared in the same manner as described hereabove for preparation of the PTFE paste dispersion 10 used to form the tubular base graft.

ii.) Extrusion of Film

[0031] The PTFE paste dispersion 20 is subsequently passed through the film extrusion dye to form a wet film extrudate 22. The wet film extrudate is taken up or wound upon a rotating core so as to form a roll of the wet film extrudate.

iii.) Calendaring

[0032] The wet film extrudate is subsequently unrolled and subjected to an initial cold (i.e., <100°c) calendaring step 24 by passing the film through at least one set of opposing stainless steel calendaring rollers having an adjustable gap thickness therebetween. The calendaring rollers are preferably maintained at a temperature between room temperature and 60°c. The width of the wet extrudate is held constant as it passes through these calendaring rollers. The thickness of the wet film extrudate is reduced to its desired final thickness [e.g. 0.010-0.013 mm (0.004-0.005 inches)] while the width of the film is maintained constant. It will be appreciated that, since the width of the film is maintained constant, the passage of the film through the calendaring machine will result in a longitudinal lengthening of the film. The amount of longitudinal lengthening will be a function of the decrease in film thickness which occurs as the film passes between the calendaring rollers.

[0033] One example of a commercially available calendaring machine useable for this purpose is the small Killion 2 Roll Stack, (Killion Extruders, Inc., Cedar Grove, NJ 07009.)

iv) Drying

[0034] Thereafter, the wet film is subjected to a drying step 26. This drying step may be accomplished by permitting or causing the liquid lubricant to evaporate from the matrix of the film. Such evaporation of the liquid lubricant may be facilitated by passing the film over a drum or roller which is maintained in an elevated temperature sufficient to cause the liquid lubricant to fully evaporate from the film matrix.

v) Expansion

[0035] Separately, or concurrently with the drying step 26, the film is subjected to an expansion step 28. Such expansion step comprises expanding the PTFE film in at least one direction (e.g., longitudinally). Such expansion of the film serves to a) increase the porosity of the film, b) increase the strength of the film, and c) orient the PTFE fibrils in the direction of the axis of expansion. This expansion step 28 is typically carried out with some heating of the film during such expansion, but such heating does not exceed the crystalline melting point of the PTFE polymer.

vi) Sintering

[0036] After the drying step 26 and expansion step 28 have been completed, the film is subjected to a sintering step 30 wherein the film is heated to a temperature above the melting point of PTFE to accomplish sintering or amorphous locking of the PTFE polymer. This sintering step 30 may be carried out by passing the film over a drum or roller which is maintained at a high surface temperature (e.g., 350-420°c) to cause the desired heating of the PTFE film above the melting point of the PTFE polymer for a sufficient period of time to effect the desired sintering of the film.

C. Wrapping and Lamination of the Reinforcement-Tape onto the Base Graft

[0037] After the sintered PTFE base graft and sintered PTFE reinforcement tape have been separately prepared, the tape-reinforced tubular graft is fabricated by spirally wrapping the PTFE reinforcement tape onto the outer surface of the tubular base graft 32. Thereafter, the tape is laminated or fused onto the outer surface of the graft 34.

[0038] Typically, in carrying out these steps (i.e., winding of the tape 32 and lamination 34 of the method, a first rigid stainless steel rod or mandrel, having an outer diameter substantially the same as the lumenal diameter of the sintered expanded tubular extrudate (i.e., the base graft) is inserted into the lumen of the base graft. Thereafter, the mandrel-borne sintered PTFE tubular base graft is rotated or spun about its longitudinal axis while the strips of expanded, sintered PTFE reinforcement tape are laid on the outer surface of the base graft, thereby spirally wrapping the tape onto the base graft to form the desired tape-reinforced graft structure. The ends of the tape reinforced graft are then affixed to the first mandrel by way of wire ligatures, thereby preventing the tape-reinforced graft from longitudinal shortening.

[0039] The mandrel-borne, tape-reinforced graft is then placed in an oven and heated to a temperature of approximately 355-375°c for a period of approximately 10-60 minutes to cause the sintered PTFE reinforcement tape to become laminated to the outer surface of the sintered PTFE base graft.

[0040] The presence of the first rigid mandrel within the lumen of the tape-reinforced graft prevents the tape-reinforced graft from undergoing radial shrinkage or contraction during this lamination step. Also, the wire ligatures affixing the nds of the tape-reinforced graft to the rigid mandrel prevent the graft from undergoing longitudinal shrinkage or shortening during this lamination step.

D. Radial Shrinkage of the Tape-Reinforced Graft

[0041] After the tape has been laminated onto the outer surface of the base graft to form the desired tape-reinforce graft structure, the tape-reinforced graft is subjected to radial shrinkage 36. This radial shrinkage step 36 may be carried out in one or more increments or stages.

[0042] In accordance with the preferred method, the radial shrinkage of the graft may be carried out by initially removing the wire ligatures which held the graft to the first rigid mandrel, and removing the first rigid mandrel from the lumen of the graft.

[0043] Thereafter, a second rigid mandrel, having an outer diameter which is smaller than the outer diameter of the first rigid mandrel, is inserted through the lumen of the graft, and the ends of the graft are affixed, by way of wire ligatures, to the second rigid mandrel.

[0044] Thereafter, the second rigid mandrel and the tape-reinforced graft disposed thereon are placed back in the oven at a temperature of 355°c for a period of approximately 10 minutes to cause the graft to undergo radial shrinkage until the lumenal diameter of the graft has become substantially the same as the outer diameter of the second rigid mandrel.

[0045] Thereafter, the wire ligatures are removed and the second rigid mandrel is extracted from the lumen of the graft.

[0046] A third rigid mandrel, having an outer diameter which is smaller than the outer diameter of the second rigid mandrel, is then inserted through the lumen of the graft and wire ligatures are utilized to affix the ends of the graft to the third rigid mandrel.

[0047] Thereafter, the third rigid mandrel, along with the tape-reinforced graft disposed thereon, is placed in an oven at a temperature of 355°c for a period of approximately 10 minutes to cause the graft to undergo further radial shrinkage until the lumenal diameter of the graft is substantially the same as the outer diameter of the third rigid mandrel.

[0048] The above-described shrinkage steps may be repeated consecutively using a number of progressively smaller rigid mandrels to effect incremental (e.g., staged) radial shrinkage of the graft. Care is taken to firmly affix the ends of the graft to each rigid mandrel prior to shrinkage thereof, so as to prevent the graft from undergoing longitudinal shrinkage or longitudinal shortening during the radial shrinkage process.

[0049] Although any suitable number of incremental shrinkage steps may be utilized, it is expected that in most applications the desired radial shrinkage of the graft will be accomplished with the use of no more than five (5) progressively smaller rigid mandrels.

[0050] For example, if it is desired to manufacture a tape-reinforced tubular graft which will have a lumenal diameter, when fully expanded, of 12.7 mm (0.5 Inch), it will be desirable to initially manufacture the tape-reinforced graft structure to have such 12.7 mm (0.5 inch) lumenal diameter prior to shrinkage thereof. Thereafter, the tape-reinforced graft structure may be subjected to incremental shrinkage of reduced diameter mandrels such as shown in the following example:

Example	
Preparation of A Radially Enlargeable Graft Having an OD of 0.3 Inches*	
MANDREL NO.	MANDREL OUTER DIAMETER
1	0.5 inch
2	0.45 inch
3	0.4 inch
4	0.35 inch
5	0.3 inch

* 1 inch = 25.4 mm.

[0051] Thus, by incrementally shrinking the graft onto the outer surfaces of the five (5) shrinking mandrels listed hereabove, the lumenal diameter of the graft will be reduced from an initial lumenal diameter of 12.7 mm (0.5 inches) to a final lumenal diameter of 7.6 mm (0.3 inches).

[0052] The tape-reinforced graft described hereabove, having a lumenal diameter of 7.6 mm (0.3 inches), may then be re-expanded to a fully expanded diameter of approximately 12.7 mm (0.5 inches)--the same as its original diameter prior to shrinkage.

[0053] The incremental or step-wise shrinkage of the graft is for the purpose of preventing puckering or wrinkling of the graft as may occur if a large amount of radial shrinkage is effected in a single step. Although this increm ntal or step wise shrinkage is described hereabove with reference to a batch manufacturing method whereby individual segments of the graft material are placed on progressively smaller rigid mandrels or rods, it will be appreciated that the method of the present invention may also be carried out by various continuous techniques whereby the radial shrinkage of the graft will occur gradually, without puckering or wrinkling of the tubular base graft. For example, a continuous elongate tubular tape-reinforced graft may be drawn longitudinally over the surface of a gradually tapered or gradually narrowed rigid mandrel while heat is applied thereto to bring about the desired gradual radial shrinkage of the graft as it passes over the outer surface of the tapered or narrowed rigid mandrel. Alternatively, a segment of tape-reinforced tubular graft material may be initially placed on a single mandrel of adjustable or shrinkable diameter such that the mandrel will decrease or shrink in diameter as the graft shrinks in diameter.

[0054] It is intended that the present invention, as claimed herebelow, include any and all such continuous embodiments and/or adjustable/shrinkable mandrel embodiments of the method, as well as the specific batch-preparation method described hereabove. The radially shrunken tape-reinforced tubular PTFE grafts formed by the above-set-forth method may be cut into desired lengths, sterilized by gas or other suitable sterilization method(s), and packaged for distribution and subsequent implantation in a mammalian host.

[0055] It will be appreciated that the radially shrunken tape-reinforced PTFE vascular grafts of the present invention may be used in applications wherein they are anastomosed into a host blood vessel by known open surgical techniques, without being subjected to radial enlargement at the time of implantation of the graft. In these applications, one advantage which may be achieved through the use of the radially shrunken graft material is improved suture holding strength and a decreased likelihood of suture tear through when the ends of the graft are anastomosed to the host blood vessel.

[0056] Also, the radially shrunken tape-reinforced PTFE grafts of the present invention may be used in a variety of endovascular applications wherein they will be radially expanded or radially dilated at the time of implantation. In this regard, the radially expandable vascular grafts of the present invention may be used in conjunction with various presently known or hereafter invented anchoring devices, stents, or other support systems for affixing and holding the graft at its desired position within the lumen of a mammalian blood vessel.

F. Additional External Reinforcement

[0057] In some applications, it is desirable for the grafts manufactured by the method of the present invention to include an external reinforcement member, such as a PTFE filament wound spirally about and fused to the outer surface of the tape-reinforced graft. The type(s) of PTFE filaments used to form such reinforcement member are typically sufficiently stretchable to accommodate and undergo the desired amount of radial expansion or radial stretching of the tape-reinforced graft. Thus, it is possible to apply and affix such PTFE filament reinforcement member by traditional methods, after the tape-reinforced graft has been radially shrunk.

[0058] In accordance with the invention, in embodiments where it is desired to provide a PTFE reinforcement filament on the outer surface of the graft, the radially shrunken tape-reinforced graft provided at the end of the radial shrinkage step 36 may be positioned on a rigid mandrel having an outer diameter equal to the shrunken inner diameter of the graft lumen. Thereafter, a sintered PTFE monofilament bead, such as that commercially available as PTFE beading, (Zeus Industrial Products, Inc., Orangeburg, S.C.) is spirally wound about the outer surface of the tape-reinforced tubular graft 38.

[0059] Thereafter, the mandrel-borne tape-reinforced vascular graft having the PTFE filament spirally wound thereon is placed in an oven and heated to a temperature which is sufficient to fuse or laminate the PTFE reinforcement filament to the outer surface of the tape-reinforced graft 40.

[0060] It will be appreciated that alternative methods of fusing the beading to the outer surface of the graft may also be employed.

[0061] When so manufactured, the PTFE filament applied to the outer surface of the graft will undergo radial expansion or radial stretching concurrently with the remainder of the tape-reinforced graft prepared in accordance with the above-described method of the present invention.

2.Alternative method for forming the Radially Expandable, Tape-Reinforced Graft

[0062] As an alternative to the above-described method, wherein the entire tape-reinforced graft (i.e., the reinforcement tape in combination with the tubular base graft) is subjected to radial shrinkage, the radially expandable tape-reinforced graft of the present invention may also be manufactured by an alternative method wherein only the rein-

forcement tape is subjected to radial shrinkage, and such radially shrunken reinforcement tape is subsequently applied to a relatively small diameter tubular base graft such that the base graft-reinforcement tape combination is capable of subsequently undergoing radial enlargement without tearing or breaking of the reinforcement tape.

[0063] This alternative method is shown in the block diagram of Figure 2.

i. Preparation of Small Diameter Base Graft

[0064] A relatively small diameter tubular base graft is prepared of expanded sintered PTFE material by the same steps 10 through 18 as described hereabove. However, in this method, the tubular base graft is of a diameter which is equal to the desired diameter of the final tape-reinforced graft after radial shrinkage thereof. The tubular base graft is preferably a thin walled or ultra-thin walled graft capable of undergoing more than 5% radial enlargement without tearing or breaking.

ii) Preparation of PTFE Reinforcement Tape Tube

[0065] Also, in this method, a quantity of expanded sintered PTFE reinforcement tape is prepared by the same steps 20 through 30 as described hereabove. Thereafter, the expanded sintered PTFE reinforcement tape is used to prepare a "tape-tube" and such tape tube is subsequently subjected to radial shrinkage, then applied to the outer surface of the small diameter thin or ultra-thin walled base graft.

[0066] Specifically, as shown in Figure 2, the tape-tube may by prepared by initially wrapping 80 the expanded sintered PTFE reinforcement tape around a rigid mandrel in overlapping or otherwise abutting convolutions, to form an elongate, tubular tape configuration. The mandrel-borne tape is then placed in an oven or otherwise heated to a temperature which causes the convolutions of tape to laminate or fuse to one another, thereby forming a tape-tube 82.

[0067] Also, the tape-tube may be prepared by the methodology disclosed in US-A-5,207,960 (Moret de Rocheprise) entitled, METHOD FOR THE MANUFACTURE OF THIN TUBES OF FLUORINATED RESIN, PARTICULARLY OF POLYETRAFLUOROETHYLENE.

iii) Radial Shrinkage of Tape-Tube

[0068] The tape-tube is then subjected to radial shrinkage, by any suitable method, including any of the heat-induced or chemical-induced shrinkage methods described herein. Since the tape-tube is devoid of any internal base graft, it may be unnecessary to utilize the gradual or incremental shrinkage described hereabove, as such gradual or incremental shrinkage is primarily intended to avoid puckering or infolding of the base graft. In this regard, the tape tube may simply be placed on a small diameter mandrel, such mandrel having a diameter substantially equal to the intended diameter of the tape-tube after shrinkage thereof. The ends of the tape-tube may be affixed to the mandrel to prevent longitudinal shrinkage or longitudinal shortening of the tape-tube during the shrinkage process. Thereafter, the small diameter mandrel and the tape-tube affixed thereto may be heated to a temperature which causes the tape tube to shrink to the diameter of the mandrel. Thereafter, the tape-tube is removed from the small diameter mandrel and utilized for subsequent fabrication of the desired radially enlargeable tape-reinforced graft.

iv) Fabrication of Tape-Reinforced Graft

[0069] The radially enlargeable tape-reinforced graft is fabricated by inserting the previously prepared small diameter tubular base graft into the lumen of the radially shrunken tape-tube 86.

v) Fusion of Tape-Tube to Base Graft

[0070] Thereafter, the tape-tube/base graft combination is heated or otherwise treated to cause the tape-tube to fuse to the outer surface of the base graft, 88. Such fusion of the tape-tube to the outer surface of the base graft, results in the formation of the desired radially enlargeable tape-reinforced graft.

[0071] In a variation of the above, described alternative method, the reinforcement tape may be longitudinally shrunk, without being formed into a tape-tube as described hereabove. Such longitudinally shrunken tape may then be spirally wrapped around, and laminated to a relatively small diameter base graft--in accordance with the above-described wrapping and lamination methods, thereby forming a radially enlargeable tape-reinforced graft.

[0072] The radially enlargeable vascular grafts of the present invention, as discussed hereabove, may be utilized in the manufacture of endovascular grafting systems which are deployable into the lumen of a blood vessel through a catheter or other tubular introducer and subsequently radially expandable such that the lumen of the graft will approximate the lumenal size of the blood vessel wherein the graft is disposed, and the graft will become anchored or affixed

to the surrounding blood vessel wall.

[0073] It will be appreciated that in many such endovascular applications, it will be desirable to utilize th radially enlargeabl tape-reinforced vascular graft of the present invention in conjunction with one or mor a) anchoring mechanisms, b) stents or c) other fixation devices, for the purpose of securing and affixing th graft to the surrounding blood vessel wall. Examples of endovascular graft affixation devices, stents and/or oth r means which may be used for supporting or affixing an endoluminally positioned tubular graft of the present invention are described in the following United States and foreign patents/patent publications: 4,733,665 (Palmaz), 4,776,337 (Palmaz), 5,037,392 (Hillstead), 5,116,318 (Hillstead), 5,135,536 (Hillstead), 5,21,658 (Clouse), 5,219,355 (Parodi et al.), 5,275,622 (Lazarus et al.), 5,282,824 (Gianturco), 5,292,331 (Boneau), 5,330,500 (Song), 5,354,308 (Simon et al), 5,360,443 (Borone et al), 5,015,253 (MacGregor), 5,171,262 (MacGregor), 5,061,275 (Wallsten et al.), 5,282,860 (Matsuno et al.), 5,290,305 (Inoue), 5,304,200 (Spaulding), 5,306,286 (Stack et al.), DT197808 (Choudhury), SU 1217-402-A (Khark), EP 466-518-A (Harrison et al.), EP 579523-A1 (Cottenceau J., et al.), 2,189,150-A (Medinvent), and WO 90/02641 (Bowald et al.).

[0074] Also, in endovascular applications wherein it is desired to radially enlarge the graft in situ, it will be appreciated that various types of expansion apparatus may be used to cause the desired radial expansion or radial stretching of the graft. In particular, a generally cylindrical balloon may be formed on the outer surface of a catheter and inserted within the lumen of the shrunken graft during or after placement of the graft within the lumen of the host blood vessel. Thereafter, the balloon may be inflated to cause controlled radial expansion of the graft. After being fully radially enlarged, the graft may be affixed or anchored to the surrounding blood vessel wall.

[0075] The grafts of the present invention may also find utility in traditional open surgical implantation methods wherein it is desired to provide a graft having improved strength and improved resistance to suture pull-through. In this regard, radially shrunken endovascular grafts of the present invention may be provided for surgical implantation by traditional open surgical techniques wherein a radially shrunken vascular graft of the present invention is anastomosed into the host blood vessel to replace or bypass a diseased, or damaged segment of the vessel. In this regard, the shrunken size of the graft will be matched to the size of the host blood vessel, and the graft will be sutured in place without effecting any radial enlargement of the graft. The radial shrinkage of the graft which took place during the manufacturing process will have imparted substantial improvements to the overall strength and suture holding properties of the graft, even though no radial enlargement of the graft is effected at the time of implantation.

[0076] The radial shrinkage of the reinforcement tape, or of the entire tape-reinforced tubular graft, may be accomplished by any suitable method other than the heat-induced shrinkage methods described specifically herein, including the use of any suitable chemical shrinkage technique whereby exposure of the reinforcement tape and/or the entire tape-reinforced graft to a particular chemical will cause the reinforcement tape and/or the entire tape-reinforced graft to undergo the desired radial shrinkage.

Claims

1. A method for manufacturing a radially enlargeable tape-reinforced tubular vascular graft, said method comprising the steps of:

   a) providing a workpiece comprising:

      i. a tubular base graft having an outer surface and a hollow lumen extending longitudinally therethrough, said tubular base graft being formed substantially of a sintered fluoropolymer material; and

      ii. reinforcement tape wound about the outer surface of said tubular base graft, said reinforcement tape comprising a film formed substantially of sintered fluoropolymer material; and

   b) radially shrinking said workpiece, thereby causing the graft to assume a radially shrunken state from which said graft may be subsequently radially enlarged.

2. The method of Claim 1 wherein said method further comprises the step of:
   c) preventing the workpiece from undergoing longitudinal shortening while said workpiece is undergoing the radial shrinkage of step b.

3. The method of Claim 1 wherein step b comprises:

   initially radially shrinking the workpiece by a first incremental amount; and,
   subsequently radially shrinking the workpiece by at least one additional incremental amount.

4. The method of Claim 3 wherein the step of "subsequently radially shrinking the workpiece by at least one additional incremental amount" comprises:
radially shrinking the workpiece by a second incremental amount.

5. The method of Claim 4 wherein step b further comprises:
subsequently radially shrinking the workpiece by a third incremental amount.

6. The method of Claim 5 wherein step b further comprises:
subsequently radially shrinking the workpiece by a fourth incremental amount.

7. The method of Claim 6 wherein step b further comprises:
subsequently radially shrinking the workpiece by a fifth incremental amount.

8. The method of Claim 1 wherein the lumen of the tubular base graft of the workpiece provided in step a, has a first lumenal diameter prior to undergoing radial shrinkage in step b of the method, and wherein step b of the method comprises:

providing a first shrinkage mandrel having an outer diameter which is smaller than the lumenal diameter of the graft;
inserting said first shrinkage mandrel into the lumen of the workpiece;
heating the workpiece to cause the workpiece to radially shrink until the lumenal diameter of the workpiece is substantially the same as the outer diameter of said first shrinkage mandrel.

9. The method of Claim 8 wherein step b of said method further comprises:

removing said first shrinkage mandrel from the lumen of the workpiece;
providing a second shrinkage mandrel having an outer diameter which is smaller than the outer diameter of said first shrinkage mandrel;
inserting said second shrinkage mandrel into the lumen of the workpiece; and,
heating the workpiece to cause the workpiece to radially shrink until the lumenal diameter of the workpiece is substantially the same as the outer diameter of the second shrinkage mandrel.

10. The method of Claim 9 wherein step b of said method further comprises:

removing said second shrinkage mandrel from the lumen of the workpiece;
providing a third shrinkage mandrel having an outer diameter which is smaller than the outer diameter of said second shrinkage mandrel;
inserting said third shrinkage mandrel into the lumen of the workpiece; and,
heating the workpiece to cause the workpiece to radially shrink until the lumenal diameter of the workpiece is substantially the same as the outer diameter of the third shrinkage mandrel.

11. The mandrel of Claim 10, wherein step b, further comprises:

providing a fourth shrinkage mandrel having an outer diameter which is smaller than the outer diameter of the third shrinkage mandrel;
inserting said fourth shrinkage mandrel into the lumen of the workpiece and,
heating the workpiece to cause the workpiece to radially shrink until the lumenal diameter of the workpiece is substantially the same as the outer diameter of the fourth shrinkage mandrel.

12. The method of Claim 11 wherein step b further comprises:

removing the fourth shrinkage mandrel from the lumen of the workpiece;
providing a fifth shrinkage mandrel having an outer diameter which is smaller than the outer diameter of the fourth shrinkage mandrel;
inserting said fifth shrinkage mandrel into the lumen of the workpiece; and,
heating the workpiece to cause the workpiece to radially shrink until the lumenal diameter of the workpiece is substantially the same as the outer diameter of the fifth shrinkage mandrel.

13. The method of Claim 1 wherein the tubular base graft of the workpiece is formed of expanded, sintered PTFE.

14. The method of Claim 1 wherein the reinforcement tape of the workpiec is formed substantially of expanded, sintered PTFE.

15. The method of Claim 3 wherein said method further comprises the step of:
c) preventing the workpiece from undergoing longitudinal shortening while said workpiece is undergoing the radial shrinkage of step b.

16. The method of Claim 9 wherein said method further comprises the step of:
c) preventing the workpiece from undergoing longitudinal shortening while said workpiece is undergoing the radial shrinkage of step b.

17. The method of any preceding claim, comprising
providing an anchoring apparatus for anchoring said graft to the wall of a blood vessel after the graft has been i) positioned endoluminally and ii) radially expanded within the lumen of said blood vessel.

18. The method of Claim 1 wherein step b comprises:
radially shrinking said workpiece so that the radial dimension of the workpiece is decreased by more than 5%.

19. The method of Claim 1 wherein step b comprises:
radially shrinking said workpiece such that the radial dimension of said workpiece is decreased by more than 10%.

20. The method of Claim 1 wherein step b comprises:
radially shrinking said workpiece such that the radial dimension of said workpiece is decreased by more than 20%.

21. The method of Claim 1 wherein step b comprises:
radially shrinking said workpiece such that the radial dimension of said workpiece is decreased by more than 40%.

22. A batch method for manufacturing a radially expandable, tape-reinforced, tubular vascular graft formed substantially of sintered PTFE, said method comprising the steps of:

a) providing a tubular base graft formed of expanded, sintered PTFE, said tube having a first end, a second end, an outer surface, and a lumen of a first diameter extending longitudinally therethrough;
b) providing a quantity of PTFE reinforcement tape, said tape comprising an expanded, sintered PTFE film having a thickness of 2.5-76.2 μm (0.0001-0.003 inches);
c) inserting a first rigid mandrel into the lumen of said tubular base graft, said first rigid mandrel having an outer diameter which is substantially equal to the first lumenal diameter of said tubular base graft;
d) spirally wrapping said reinforcement tape about the outer surface of said tubular base graft to form a tape-reinforced graft;
e) heating said tape-reinforced graft to a temperature above 327°c for a sufficient period of time to cause said reinforcement tape to laminate to the outer surface of said tubular base graft;
f) removing said first mandrel from the lumen of the tape-reinforced graft;
g) inserting a second rigid mandrel into the lumen of the tape-reinforced graft, said second rigid mandrel having an outer diameter which is smaller than the first lumenal diameter of the lumen of said tape- reinforced graft;
h) again heating the tape-reinforced graft to a temperature sufficient to cause the tape-reinforced graft to shrink radially until its lumenal diameter is substantially the same as the outer diameter of the second rigid mandrel.

23. The method of Claim 22 further comprising the steps of:

i) removing said second rigid mandrel from the lumen of said tape-reinforced graft;
j) inserting a third rigid mandrel into the lumen of said tape-reinforced graft, said third rigid mandrel having an outer diameter which is smaller than the outer diameter of second rigid mandrel;
k) again heating the tape-reinforced graft to a temperature sufficient to cause further radial shrinkage of said graft until the lumenal diameter of the tape-reinforced graft is substantially the same as the outer diameter of

said third rigid mandrel.

24. The method of Claim 23 further comprising the steps of:

1) removing said third rigid mandrel from the lumen of said tape-reinforced graft;
m) inserting a forth rigid mandrel into the lumen of said tape-reinforced graft, said third rigid mandrel having an outer diameter which is smaller than the outer diameter of said third rigid mandrel;
n) again heating the tape-reinforced graft to a temperature sufficient to cause further radial shrinkage of the graft until its lumenal diameter is substantially the same as the outer diameter of said fourth rigid mandrel.

25. The method of Claim 24 further comprising the steps of:

o) removing said fourth rigid mandrel from the lumen of said tape-reinforced graft;
p) inserting a fifth rigid mandrel into the lumen of said tape-reinforced graft, said fifth rigid mandrel having an outer diameter which is smaller than the outer diameter of said fourth rigid mandrel;
q) again heating said tape-reinforced graft to a temperature sufficiently to effect further radial shrinkage of said tape-reinforced graft until its lumenal diameter is substantially the same as the outer diameter of said fifth rigid mandrel.

26. The method of Claim 22, wherein step d, further comprises affixing the ends of the tape-reinforced graft to said first mandrel to prevent longitudinal shortening of the tape-reinforced graft during subsequent heating thereof in step e.

27. The method of Claim 22 wherein step g, further comprises affixing the ends of the tape-reinforced tubular graft to the second rigid mandrel to prevent longitudinal shortening of the tape-reinforced graft during subsequent heating in step h.

28. The method of Claim 23 wherein step j, further comprises fixing the ends of said tape-reinforced graft to said third rigid mandrel to prevent longitudinal shortening of the tape-reinforced graft during subsequent heating in step k.

29. The method of Claim 24 wherein step m, further comprises affixing the ends of said tape-reinforced graft to the outer surface of said fourth rigid mandrel to prevent longitudinal shortening of the tape-reinforced graft during subsequent heating in step n.

30. The method of Claim 25 wherein step p, further comprises affixing the ends of said tape-reinforced graft to said fifth rigid mandrel to prevent longitudinal shortening of the tape-reinforced graft during subsequent heating in step q.

31. A method of manufacturing a radially enlargeable tape-reinforced tubular vascular graft, said method comprising the steps of:

a) forming a tape-tube by wrapping a quantity of expanded, sintered fluoropolymer tape about a rigid mandrel and subsequently heating said tape to form said tape-tube;
b) radially shrinking said tape-tube;
c) coaxially positioning a tubular base graft formed of expanded, sintered fluoropolymer, within said tape-tube;
d) causing said tape-tube to become affixed to said base graft, thereby forming said radially enlargeable tape-reinforced tubular vascular graft.

32. The method of Claim 31 wherein said method further comprises the step of:
e) preventing the tape-tube from undergoing longitudinal shortening while said tube is undergoing the radial shrinkage of step b.

33. The method of Claim 32 wherein step c, further comprises:
coaxially positioning a thin-walled tubular base graft having a thickness in the range of 0.15-0.65mm within said tape-tube.

34. The method of Claim 32 wherein step c, further comprises:
coaxially positioning a ultra-thin-walled tubular base graft having a thickness of less than 0.15mm within said tape-tube.

35. The method of Claim 31 wherein the tape utilized in step a, is formed of expanded sintered PTFE.

36. The method of Claim 31 wherein the tubular base graft used in step c, is formed of expanded sintered PTFE.

37. A method of manufacturing a radially enlargeable tape-reinforced tubular vascular graft, said method comprising the steps of:

a) providing a quantity of expanded, sintered fluoropolymer tape;
b) shrinking said expanded, sintered fluoropolymer tape;
c) providing a tubular base graft formed of expanded fluoropolymer, said tubular base graft having a lumen and an outer surface;
d) wrapping the shrunken, expanded, sintered fluoropolymer tape onto the outer surface of said tubular base graft;
e) causing said tape to become affixed to the outer surface of said tubular base graft, thereby forming said radially enlargeable tape-reinforced tubular vascular graft.

38. The method of Claim 37 wherein step c, further comprises:
providing a thin-walled tubular base graft having a thickness in the range of 0.15-0.65mm.

39. The method of Claim 37 wherein step c, further comprises:
providing an ultra-thin-walled tubular base graft having a thickness of less than 0.15mm.

40. The method of Claim 37 wherein the tape provided in step a, if formed of expanded, sintered PTFE.

41. The method of Claim 37 wherein the tubular base graft provided in step c, is formed of expanded, sintered PTFE.

Patentansprüche

1. Verfahren zum Herstellen eines radial erweiterbaren, bandverstärkten, rohrförmigen Gefäßtransplantats, wobei das Verfahren folgende Schritte aufweist:

a) Herstellen eines Werkstücks, das folgendes aufweist:

(i.) ein rohrförmiges Basistransplantat mit einer äußeren Oberfläche und einem hohlen Lumen, das sich in Längsrichtung durch das Basistransplantat hindurch erstreckt, wobei das rohrförmige Basistransplantat im wesentlichen aus einem gesinterten Fluorpolymermaterial gebildet wird;
(ii.) ein um die äußere Oberfläche des rohrförmigen Basistransplantats herumgewickeltes Verstärkungsband, wobei das Verstärkungsband eine Schicht aufweist, die im wesentlichen aus gesintertem Fluorpolymermaterial gebildet wird; und

b) radiales Schrumpfen des Werkstücks, so daß das Transplantat dazu veranlaßt wird, einen radial geschrumpften Zustand anzunehmen, von dem ausgehend das Transplantat anschließend radial erweitert werden kann.

2. Verfahren nach Anspruch 1,
das weiterhin folgenden Schritt aufweist:
c) Verhindern, daß das Werkstück eine Verkürzung in Längsrichtung erfährt, während das Werkstück der radialen Schrumpfung des Schrittes b) unterzogen wird.

3. Verfahren nach Anspruch 1,
wobei der Schritt b) folgendes aufweist:

- anfängliches radiales Schrumpfen des Werkstücks um einen ersten Inkrementbetrag; und
- anschließendes radiales Schrumpfen des Werkstücts um mindestens einen zusätzlichen Inkrementbetrag.

4. Verfahren nach Anspruch 3,
wobei der Schritt des "anschließenden radialen Schrumpfens des Werkstücks um mindestens einen zusätzlichen

Inkrementbetrag" folgendes aufweist:

- radiales Schrumpfen des Werkstücks um einen zweiten Inkrementbetrag.

5. Verfahren nach Anspruch 4,
wobei der Schritt b) ferner folgendes aufweist:

- anschließendes radiales Schrumpfen des Werkstücks um einen dritten Inkrementbetrag.

6. Verfahren nach Anspruch 5,
wobei der Schritt b) ferner folgendes aufweist:

- anschließendes radiales Schrumpfen des Werkstücks um einen vierten Inkrementbetrag.

7. Verfahren nach Anspruch 6,
wobei der Schritt b) ferner folgendes aufweist:

- anschließendes radiales Schrumpfen des Werkstücks um einen fünften Inkrementbetrag.

8. Verfahren nach Anspruch 1,
wobei das Lumen des rohrförmigen Basistransplantats des im Schritt a) gebildeten Werkstücks, bevor es einer radialen Schrumpfung in Schritt b) des Verfahrens unterzogen wird, einen ersten Lumendurchmesser aufweist und wobei der Schritt b) des Verfahrens folgendes aufweist:

- Vorsehen eines ersten Schrumpf-Dorns, der einen Außendurchmesser aufweist, der kleiner ist als der Lumendurchmesser des Transplantats;
- Einführen des ersten Schrumpf-Dorns in das Lumen des Werkstücks;
- Erwärmen des Werkstücks, um das Werkstück zum radialen Schrumpfen zu veranlassen, bis der Lumendurchmesser des Werkstücks im wesentlichen mit dem Außendurchmesser des ersten Schrumpf-Dorns übereinstimmt.

9. Verfahren nach Anspruch 8,
wobei der Schritt b) des Verfahrens ferner folgendes aufweist:

- Entfernen des ersten Schrumpf-Dorns aus dem Lumen des Werkstücks;
- Vorsehen eines zweiten Schrumpf-Dorns mit einem Außendurchmesser, der kleiner ist als der Außendurchmesser des ersten Schrumpf-Dorns;
- Einführen des zweiten Schrumpf-Dorns in das Lumen des Werkstücks; und
- Erwärmen des Werkstücks, um das Werkstück zum radialen Schrumpfen zu veranlassen, bis der Lumendurchmesser des Werkstücks im wesentlichen mit dem Außendurchmesser des zweiten Schrumpf-Dorns übereinstimmt.

10. Verfahren nach Anspruch 9,
wobei der Schritt b) des Verfahrens ferner folgendes aufweist:

- Entfernen des zweiten Schrumpf-Dorns aus dem Lumen des Werkstücks;
- Vorsehen eines dritten Schrumpf-Dorns mit einem Außendurchmesser, der kleiner ist als der Außendurchmesser des zweiten Schrumpf-Dorns;
- Einführen des dritten Schrumpf-Dorns in das Lumen des Werkstücks; und
- Erwärmen des Werkstücks, um das Werkstück zum radialen Schrumpfen zu veranlassen, bis der Lumendurchmesser des Werkstücks im wesentlichen mit dem Außendurchmesser des dritten Schrumpf-Dorns übereinstimmt.

11. Verfahren nach Anspruch 10,
wobei der Schritt b) ferner folgendes aufweist:

- Vorsehen eines vierten Schrumpf-Dorns mit einem Außendurchmesser, der kleiner ist als der Außendurchmesser des dritten Schrumpf-Dorns;

- Einführen des vierten Schrumpf-Doms in das Lumen des Werkstücks; und
- Erwärmen des Werkstücks, um das Werkstück zum radialen Schrumpfen zu veranlassen, bis der Lumendurchmesser des Werkstücks im w sentlichen mit dem Außendurchmesser des vierten Schrumpf-Doms übereinstimmt.

12. Verfahren nach Anspruch 11, wobei der Schritt b) ferner folgendes aufweist:

- Entfernen des vierten Schrumpf-Doms aus dem Lumen des Werkstücks;
- Vorsehen eines fünften Schrumpf-Doms mit einem Außendurchmesser, der kleiner ist als der Außendurchmesser des vierten Schrumpf-Doms;
- Einführen des fünften Schrumpf-Doms in das Lumen des Werkstücks; und
- Erwärmen des Werkstücks, um das Werkstück zum radialen Schrumpfen zu veranlassen, bis der Lumendurchmesser des Werkstücks im wesentlichen mit dem Außendurchmesser des fünften Schrumpf-Doms übereinstimmt.

13. Verfahren nach Anspruch 1, wobei das rohrförmige Basistransplantat des Werkstücks aus expandiertem gesintertem PTFE gebildet wird.

14. Verfahren nach Anspruch 1, wobei das Verstärkungsband des Werkstücks im wesentlichen aus expandiertem gesintertem PTFE gebildet wird.

15. Verfahren nach Anspruch 3, wobei das Verfahren ferner folgenden Schritt aufweist: c) Verhindern, daß das Werkstück eine Verkürzung in Längsrichtung erfährt, während das Werkstück der radialen Schrumpfung des Schrittes b) unterzogen wird.

16. Verfahren nach Anspruch 9, wobei das Verfahren ferner folgenden Schritt aufweist: c) Verhindern, daß das Werkstück eine Verkürzung in Längsrichtung erfährt, während das Werkstück der radialen Schrumpfung des Schrittes b) unterzogen wird.

17. Verfahren nach einem der vorausgehenden Ansprüche, bei dem eine Verankerungseinrichtung vorgesehen wird, um das Transplantat an der Wand eines Blutgefäßes zu verankern, nachdem das Transplantat i) endoluminal positioniert worden ist und ii) in dem Lumen des Blutgefäßes radial erweitert worden ist.

18. Verfahren nach Anspruch 1, wobei der Schritt b) folgendes aufweist:

- radiales Schrumpfen des Werkstücks derart, daß die radiale Abmessung des Werkstücks um mehr als 5 % vermindert wird.

19. Verfahren nach Anspruch 1, wobei der Schritt b) folgendes aufweist:

- radiales Schrumpfen des Werkstücks derart, daß die radiale Abmessung des Werkstücks um mehr als 10 % vermindert wird.

20. Verfahren nach Anspruch 1, wobei der Schritt b) folgendes aufweist:

- radiales Schrumpfen des Werkstücks derart, daß die radiale Abmessung des Werkstücks um mehr als 20 % vermindert wird.

21. Verfahren nach Anspruch 1, wobei der Schritt b) folgendes aufweist:

- radiales Schrumpfen des Werkstücks derart, daß die radiale Abmessung des Werkstücks um mehr als 40 % vermindert wird.

22. Verfahren zum chargenweisen Herstellen ines radial erweiterbaren, bandverstärkten, rohrförmigen Gefäßtransplantats, das im wesentlichen aus gesintertem PTFE gebildet wird, wobei das Verfahren folgende Schritte aufweist:

a) Herstellen ines rohrförmigen Basistransplantats aus expandiertem gesintertem PTFE, wobei das Rohrel ment ein rstes Ende, ein zweites Ende, eine äußere Oberfläche sowie in Lumen mit einem ersten Durchmesser aufweist, das sich in Längsrichtung durch dieses hindurch erstreckt;
b) Vorsehen einer Menge an PTFE-Verstärkungsband, wobei das Band eine expandierte, gesinterte PTFE-Schicht mit einer Dicke von 2,5 bis 76,2 um (0,0001 bis 0,003 Inch) aufweist;
c) Einführen eines ersten starren Dorns in das Lumen des rohrförmigen Basistransplantats, wobei der erste starre Dorn einen Außendurchmesser aufweist, der im wesentlichen dem ersten Lumendurchmesser des rohrförmigen Basistransplantats entspricht;
d) wendelförmiges Herumwickeln des Verstärkungsbands um die äußere Oberfläche des rohrförmigen Basistransplantats, um ein bandverstärktes Transplantat zu bilden;
e) Erwärmen des bandverstärkten Transplantats auf eine Temperatur über 327 °C für eine ausreichende Zeitdauer, um ein Auflaminieren des Verstärkungsbands auf die äußere Oberfläche des rohrförmigen Basistransplantats hervorzurufen;
f) Entfernen des ersten Dorns aus dem Lumen des bandverstärkten Transplantats;
g) Einführen eines zweiten starren Dorns in das Lumen des bandverstärkten Transplantats, wobei der zweite starre Dorn einen Außendurchmesser aufweist, der kleiner ist als der erste Lumendurchmesser des bandverstärkten Transplantats;
h) erneutes Erwärmen des bandverstärkten Transplantats auf eine ausreichende Temperatur, um ein radiales Schrumpfen des bandverstärkten Transplantats zu bewirken, bis sein Lumendurchmesser im wesentlichen mit dem Außendurchmesser des zweiten starren Dorns übereinstimmt.

23. Verfahren nach Anspruch 22,
das ferner folgende Schritte aufweist:

i) Entfernen des zweiten starren Dorns aus dem Lumen des bandverstärkten Transplantats;
j) Einführen eines dritten starren Dorns in das Lumen des bandverstärkten Transplantats, wobei der dritte starre Dorn einen Außendurchmesser aufweist, der kleiner ist als der Außendurchmesser des zweiten starren Dorns;
k) erneutes Erwärmen des bandverstärkten Transplantats auf eine ausreichend Temperatur, um ein weiteres radiales Schrumpfen des Transplantats zu bewirken, bis der Lumendurchmesser des bandverstärkten Transplantats im wesentlichen mit dem Außendurchmesser des dritten starren Dorns übereinstimmt.

24. Verfahren nach Anspruch 23,
das ferner folgende Schritte aufweist:

l) Entfernen des dritten starren Dorns aus dem Lumen des bandverstärkten Transplantats;
m) Einführen eines vierten starren Dorns in das Lumen des bandverstärkten Transplantats, wobei der vierte starre Dorn einen Außendurchmesser aufweist, der kleiner ist als der Außendurchmesser des dritten starren Dorns;
n) erneutes Erwärmen des bandverstärkten Transplantats auf eine ausreichende Temperatur, um ein weiteres radiales Schrumpfen des Transplantats zu bewirken, bis sein Lumendurchmesser im wesentlichen mit dem Außendurchmesser des vierten starren Dorns übereinstimmt.

25. Verfahren nach Anspruch 24,
das ferner folgende Schritte aufweist:

o) Entfernen des vierten starren Dorns aus dem Lumen des bandverstärkten Transplantats;
p) Einführen eines fünften starren Dorns in das Lumen des bandverstärkten Transplantats, wobei der fünfte starre Dorn einen Außendurchmesser aufweist, der kleiner ist als der Außendurchmesser des vierten starren Dorns;
q) erneutes Erwärmen des bandverstärkten Transplantats auf eine ausreichende Temperatur, um ein weiteres radiales Schrumpfen des bandverstärkten Transplantats zu bewirken, bis sein Lumendurchmesser im wesentlichen mit dem Außendurchmesser des fünften starren Dorns übereinstimmt.

26. Verfahren nach Anspruch 22,

wobei der Schritt d) ferner die Festlegung der Enden des bandverstärkten Transplantats an dem ersten Dorn beinhaltet, um eine Verkürzung des bandverstärkten Transplantats in Längsrichtung während der nachfolgenden Erwärmung desselben in dem Schritt e) zu verhindern.

27. Verfahren nach Anspruch 22,
wobei der Schritt g) ferner die Festlegung der Enden des bandverstärkten Transplantats an dem zweiten starren Dorn beinhaltet, um eine Verkürzung des bandverstärkten Transplantats in Längsrichtung während der nachfolgenden Erwärmung in dem Schritt h) zu verhindern.

28. Verfahren nach Anspruch 23,
wobei der Schritt j) ferner die Festlegung der Enden des bandverstärkten Transplantats an dem dritten starren Dorn beinhaltet, um eine Verkürzung des bandverstärkten Transplantats in Längsrichtung während der nachfolgenden Erwärmung in dem Schritt k) zu verhindern.

29. Verfahren nach Anspruch 24,
wobei der Schritt m) ferner die Festlegung der Enden des bandverstärkten Transplantats an der äußeren Oberfläche des vierten starren Dorns beinhaltet, um eine Verkürzung des bandverstärkten Transplantats in Längsrichtung während der nachfolgenden Erwärmung in dem Schritt n) zu verhindern.

30. Verfahren nach Anspruch 25,
wobei der Schritt p) ferner die Festlegung der Enden des bandverstärkten Transplantats an dem fünften starren Dorn beinhaltet, um eine Verkürzung des bandverstärkten Transplantats in Längsrichtung während der nachfolgenden Erwärmung in dem Schritt q) zu verhindern.

31. Verfahren zum Herstellen eines radial erweiterbaren, bandverstärkten, rohrförmigen Gefäßtransplantats, wobei das Verfahren folgende Schritte aufweist:

a) Herstellen einer Band-Röhre durch Herumwickeln einer Menge von expandiertem gesintertem Fluorpolymerband um einen starren Dorn sowie anschließendes Erwärmen des Bands zur Bildung der Band-Röhre;
b) radiales Schrumpfen der Band-Röhre;
c) koaxiales Positionieren eines rohrförmigen Basistransplantats, das aus expandiertem gesintertem Fluorpolymer gebildet ist, im Inneren der Band-Röhre;
d) Bewirken, daß die Band-Röhre an dem Basistransplantat befestigt wird, um dadurch das radial erweiterbare, bandverstärkte, rohrförmige Gefäßtransplantat zu bilden.

32. Verfahren nach Anspruch 31,
wobei das Verfahren ferner folgenden Schritt aufweist:
e) Verhindern, daß die Band-Röhre eine Verkürzung in Längsrichtung erfährt, während die Röhre der radialen Schrumpfung des Schritts b) unterzogen wird.

33. Verfahren nach Anspruch 32,
wobei der Schritt c) ferner folgendes aufweist:

- koaxiales Positionieren eines dünnwandigen rohrförmigen Basistransplantats, das eine Dicke im Bereich von 0,15 bis 0,65 mm aufweist, im Inneren der Band-Röhre.

34. Verfahren nach Anspruch 32,
wobei der Schritt c) ferner folgendes aufweist:

- koaxiales Positionieren eines ultradünnwandigen rohrförmigen Basistransplantats, das eine Dicke von weniger als 0,15 mm aufweist, im Inneren der Band-Röhre.

35. Verfahren nach Anspruch 31,
wobei das in Schritt a) verwendete Band aus expandiertem gesintertem PTFE gebildet wird.

36. Verfahren nach Anspruch 31,
wobei das in Schritt c) verwendete rohrförmige Basistransplantat aus expandiertem gesintertem PTFE gebildet wird.

37. V rfahren zum Herstellen eines radial erweiterbaren, bandverstärkten, rohrförmigen Gefäßtransplantats, wobei das Verfahren folgende Schritte aufweist:

a) Vors hen einer Menge von expandi rtem gesintertem Fluorpolymerband;
b) Schrumpfen d s expandierten gesinterten Fluorpolymerbands;
c) Herstellen eines rohrförmigen Basistransplantats aus expandiertem Fluorpolymer, wobei das rohrförmige Basistransplantat ein Lumen und eine äußere Oberfläche aufweist;
d) Wickeln des geschrumpften, expandierten, gesinterten Fluorpolymerbands auf die äußere Oberfläche des rohrförmigen Basistransplantats;
e) Bewirken einer Befestigung des Bands auf der äußeren Oberfläche des rohrförmigen Basistransplantats, um dadurch das radial erweiterbare, bandverstärkte, rohrförmige Gefäßtransplantat zu bilden.

38. Verfahren nach Anspruch 37,
wobei der Schritt c) ferner folgendes aufweist:

- Herstellen eines dünnwandigen rohrförmigen Basistransplantats, das eine Dicke im Bereich von 0,15 bis 0,65 mm aufweist.

39. Verfahren nach Anspruch 37,
wobei der Schritt c) ferner folgendes aufweist:

- Herstellen eines ultradünnwandigen rohrförmigen Basistransplantats, das eine Dicke von weniger als 0,15 mm aufweist.

40. Verfahren nach Anspruch 37,
wobei das in Schritt a) gebildete Band aus expandiertem, gesintertem PTFE gebildet wird.

41. Verfahren nach Anspruch 37,
wobei das in Schritt c) gebildete rohrförmige Basistransplantat aus expandiertem, gesintertem PTFE gebildet wird.

Revendications

1. Procédé pour fabriquer une greffe vasculaire tubulaire radialement extensible et renforcée par bande, ledit procédé comprenant les étapes consistant à :

a) produire une pièce comprenant :

i. une greffe de base tubulaire comprenant une surface extérieure et une lumière creuse s'étendant longitudinalement à travers celle-ci, ladite greffe de base tubulaire étant formée sensiblement d'un matériau de fluoropolymère fritté ; et
ii. une bande de renforcement enroulée autour de la surface extérieure de ladite greffe de base tubulaire, ladite bande de renforcement comprenant un film formé sensiblement de matériau de fluoropolymère fritté ; et

b) rétrécir radialement ladite pièce, de façon à amener la greffe dans un état radialement rétréci à partir duquel ladite greffe peut être ultérieurement radialement agrandie.

2. Procédé selon la revendication 1 dans lequel ledit procédé comprend également l'étape consistant à :
c) empêcher la pièce de subir un raccourcissement longitudinal pendant que ladite pièce est soumise au rétrécissement radial de l'étape b.

3. Procédé selon la revendication 1 dans lequel l'étape b comprend :

dans un premier temps, le rétrécissement radial de la pièce d'une première grandeur incrémentielle ; et, ensuite, le rétrécissement radial de la pièce d'au moins une grandeur incrémentielle supplémentaire.

4. Procédé selon la revendication 3 dans lequel l'étape "ensuite, le rétrécissement radial de la pièce d'au moins une

grandeur incrémentielle supplémentaire" comprend :
le rétrécissement radial de la pièce d'une deuxième grandeur incrémentielle.

5. Procédé selon la revendication 4 dans lequel l'étape b comprend également :
ensuite, le rétrécissement radial de la pièce d'une troisième grandeur incrémentielle.

6. Procédé selon la revendication 5 dans lequel l'étape b comprend également :
ensuite, le rétrécissement radial de la pièce d'une quatrième grandeur incrémentielle.

7. Procédé selon la revendication 6 dans lequel l'étape b comprend également :
ensuite, le rétrécissement radial de la pièce d'une cinquième grandeur incrémentielle.

8. Procédé selon la revendication 1 dans lequel la lumière de la greffe de base tubulaire de la pièce fournie dans l'étape a, possède un premier diamètre luminal avant de subir le rétrécissement radial dans l'étape b du procédé, et dans lequel l'étape b du procédé comprend :

la fourniture d'un premier mandrin de rétrécissement possédant un diamètre extérieur qui est inférieur au diamètre luminal de la greffe ;
l'insertion dudit premier mandrin de rétrécissement dans la lumière de la pièce ;
le chauffage de la pièce pour conduire la pièce à rétrécir radialement jusqu'à ce que le diamètre luminal de la pièce soit sensiblement le même que le diamètre extérieur dudit premier mandrin de rétrécissement.

9. Procédé selon la revendication 8 dans lequel l'étape b dudit procédé comprend également :

le retrait dudit premier mandrin de rétrécissement de la lumière de la pièce ;
la fourniture d'un deuxième mandrin de rétrécissement possédant un diamètre extérieur qui est inférieur au diamètre extérieur dudit premier mandrin de rétrécissement ;
l'insertion dudit deuxième mandrin de rétrécissement dans la lumière de la pièce ; et,
le chauffage de la pièce pour conduire la pièce à rétrécir radialement jusqu'à ce que le diamètre luminal de la pièce soit sensiblement le même que le diamètre extérieur du deuxième mandrin de rétrécissement.

10. Procédé selon la revendication 9 dans lequel l'étape b dudit procédé comprend également :

le retrait dudit deuxième mandrin de rétrécissement de la lumière de la pièce ;
la fourniture d'un troisième mandrin de rétrécissement possédant un diamètre extérieur qui est inférieur au diamètre extérieur dudit deuxième mandrin de rétrécissement ;
l'insertion dudit troisième mandrin de rétrécissement dans la lumière de la pièce ; et,
le chauffage de la pièce pour conduire la pièce à rétrécir radialement jusqu'à ce que le diamètre luminal de la pièce soit sensiblement le même que le diamètre extérieur du troisième mandrin de rétrécissement.

11. Procédé selon la revendication 10, dans lequel l'étape b comprend également :

la fourniture d'un quatrième mandrin de rétrécissement possédant un diamètre extérieur qui est inférieur au diamètre extérieur dudit troisième mandrin de rétrécissement ;
l'insertion dudit quatrième mandrin de rétrécissement dans la lumière de la pièce et,
le chauffage de la pièce pour conduire la pièce à rétrécir radialement jusqu'à ce que le diamètre luminal de la pièce soit sensiblement le même que le diamètre extérieur du quatrième mandrin de rétrécissement.

12. Procédé selon la revendication 11 dans lequel l'étape b comprend également :

le retrait du quatrième mandrin de rétrécissement de la lumière de la pièce ;
la fourniture d'un cinquième mandrin de rétrécissement possédant un diamètre extérieur qui est inférieur au diamètre extérieur du quatrième mandrin de rétrécissement ;
l'insertion dudit cinquième mandrin de rétrécissement dans la lumière de la pièce ; et,
le chauffage de la pièce pour conduire la pièce à rétrécir radialement jusqu'à ce que le diamètre luminal de la pièce soit sensiblement le même que le diamètre extérieur du cinquième mandrin de rétrécissement.

13. Procédé selon la revendication 1 dans lequel la greffe de base tubulaire de la pièce est formée de PTFE expansé

et fritté.

14. Procédé selon la revendication 1 dans lequel la bande de renforcement de la pièce est formée sensiblement de PTFE expansé et fritté.

15. Procédé selon la revendication 3 dans lequel ledit procédé comprend l'étape consistant à :
c) empêcher la pièce de subir un raccourcissement longitudinal pendant que ladite pièce subit le rétrécissement radial de l'étape b.

16. Procédé selon la revendication 9 dans lequel ledit procédé comprend également l'étape consistant à :
c) empêcher la pièce de subir un raccourcissement longitudinal pendant que ladite pièce subit le rétrécissement radial de l'étape b.

17. Procédé selon l'une quelconque des revendications précédentes, comprenant
la fourniture d'un appareil d'ancrage pour ancrer ladite greffe à la paroi d'un vaisseau sanguin après que la greffe ait été i) positionnée à l'intérieur de la lumière et ii) radialement dilatée dans la lumière dudit vaisseau sanguin.

18. Procédé selon la revendication 1 dans lequel l'étape b comprend :
le rétrécissement radial de ladite pièce de façon à ce que la dimension radiale de la pièce soit diminuée de plus de 5 %.

19. Procédé selon la revendication 1 dans lequel l'étape b comprend :
le rétrécissement radial de ladite pièce de façon à ce que la dimension radiale de la pièce soit diminuée de plus de 10 %.

20. Procédé selon la revendication 1 dans lequel l'étape b comprend :
le rétrécissement radial de ladite pièce de façon à ce que la dimension radiale de la pièce soit diminuée de plus de 20 %.

21. Procédé selon la revendication 1 dans lequel l'étape b comprend :
le rétrécissement radial de ladite pièce de façon à ce que la dimension radiale de la pièce soit diminuée de plus de 40 %.

22. Procédé par lot pour fabriquer une greffe vasculaire tubulaire radialement extensible, renforcée par bande formée essentiellement de PTFE fritté, ledit procédé comprenant les étapes consistant à :

a) fournir une greffe de base tubulaire formée de PTFE expansé et fritté, ledit tube comprenant une première extrémité, une deuxième extrémité, une surface extérieure, et une lumière d'un premier diamètre s'étendant longitudinalement à travers celle-ci ;
b) fournir une quantité de bande de renforcement de PTFE, ladite bande comprenant un film de PTFE expansé et fritté possédant une épaisseur de 2,5 à 76,2 µm (0,0001 à 0,003 pouce) ;
c) insérer un premier mandrin rigide dans la lumière de ladite greffe de base tubulaire, ledit premier mandrin rigide possédant un diamètre extérieur qui est sensiblement égal au premier diamètre luminal de ladite greffe de base tubulaire ;
d) enrouler en spirale ladite bande de renforcement autour de la surface extérieure de ladite greffe de base tubulaire pour former une greffe renforcée par bande ;
e) chauffer ladite greffe renforcée par bande à une température supérieure à 327°C pendant un intervalle de temps suffisant pour conduire ladite bande de renforcement à se stratifier sur la surface extérieure de ladite greffe de base tubulaire ;
f) retirer ledit premier mandrin de la lumière de la greffe renforcée par bande ;
g) insérer un deuxième mandrin rigide dans la lumière de la greffe renforcée par bande, ledit deuxième mandrin rigide possédant un diamètre extérieur qui est inférieur au premier diamètre luminal de la lumière de ladite greffe renforcée par bande ;
h) chauffer de nouveau la greffe renforcée par bande à une température suffisante pour conduire la greffe renforcée par bande à rétrécir radialement jusqu'à ce que son diamètre luminal soit sensiblement le même que le diamètre extérieur du deuxième mandrin rigide.

23. Procédé selon la revendication 22 comprenant également les étapes consistant à :

i) retirer ledit deuxième mandrin rigide de la lumière de ladite greffe renforcée par bande ;
j) insérer un troisième mandrin rigide dans la lumière de ladite greffe renforcée par bande, ledit troisième mandrin rigide possédant un diamètre extérieur qui est inférieur au diamètre extérieur du deuxième mandrin rigide ;
h) chauffer de nouveau la greffe renforcée par bande à une température suffisante pour causer le rétrécissement radial supplémentaire de ladite greffe jusqu'à ce que le diamètre luminal de la greffe renforcée par bande soit sensiblement le même que le diamètre extérieur dudit troisième mandrin rigide.

24. Procédé selon la revendication 23 comprenant également les étapes consistant à :

l) retirer ledit troisième mandrin rigide de la lumière de ladite greffe renforcée par bande ;
m) insérer un quatrième mandrin rigide dans la lumière de ladite greffe renforcée par bande, ledit quatrième mandrin rigide possédant un diamètre extérieur qui est inférieur au diamètre extérieur dudit troisième mandrin rigide ;
n) chauffer de nouveau la greffe renforcée par bande à une température suffisante pour causer le rétrécissement radial supplémentaire de la greffe jusqu'à ce que son diamètre luminal soit sensiblement le même que le diamètre extérieur dudit quatrième mandrin rigide.

25. Procédé selon la revendication 24 comprenant également les étapes consistant à :

o) retirer ledit quatrième mandrin rigide de la lumière de ladite greffe renforcée par bande ;
p) insérer un cinquième mandrin rigide dans la lumière de ladite greffe renforcée par bande, ledit cinquième mandrin rigide possédant un diamètre extérieur qui est inférieur au diamètre extérieur dudit quatrième mandrin rigide ;
q) chauffer de nouveau la greffe renforcée par bande à une température suffisante pour causer le rétrécissement radial supplémentaire de ladite greffe renforcée par bande jusqu'à ce que son diamètre luminal soit sensiblement le même que le diamètre extérieur dudit cinquième mandrin rigide.

26. Procédé selon la revendication 22, dans lequel l'étape d comprend également la fixation des extrémités de la greffe renforcée par bande audit premier mandrin pour empêcher le raccourcissement longitudinal de la greffe renforcée par bande pendant le chauffage ultérieur de celle-ci dans l'étape e.

27. Procédé selon la revendication 22, dans lequel l'étape g comprend également la fixation des extrémités de la greffe tubulaire renforcée par bande audit deuxième mandrin rigide pour empêcher le raccourcissement longitudinal de la greffe renforcée par bande pendant le chauffage ultérieur dans l'étape h.

28. Procédé selon la revendication 23, dans lequel l'étape j comprend également la fixation des extrémités de ladite greffe renforcée par bande audit troisième mandrin rigide pour empêcher le raccourcissement longitudinal de la greffe renforcée par bande pendant le chauffage ultérieur dans l'étape k.

29. Procédé selon la revendication 24, dans lequel l'étape m comprend également la fixation des extrémités de ladite greffe renforcée par bande à la surface extérieure dudit quatrième mandrin rigide pour empêcher le raccourcissement longitudinal de la greffe renforcée par bande pendant le chauffage ultérieur dans l'étape n.

30. Procédé selon la revendication 25, dans lequel l'étape p comprend également la fixation des extrémités de ladite greffe renforcée par bande audit cinquième mandrin rigide pour empêcher le raccourcissement longitudinal de la greffe renforcée par bande pendant le chauffage ultérieur dans l'étape q.

31. Procédé de fabrication d'une greffe vasculaire tubulaire renforcée par bande radialement extensible, ledit procédé comprenant les étapes consistant à :

a) former un tube de bande en enroulant une quantité de bande de fluoropolymère expansé et fritté autour d'un mandrin rigide et ensuite chauffer ladite bande pour former ledit tube de bande ;
b) rétrécir radialement ledit tube de bande ;
c) positionner de façon coaxiale une greffe de base tubulaire formée de fluoropolymère expansé et fritté dans ledit tube de bande ;
d) amener ledit tube de bande à devenir fixé à ladite greffe de base, de façon à former ladite greffe vasculaire tubulaire extensible radialement et renforcée par bande.

32. Procédé s lon la revendication 31 dans lequel ledit procédé comprend également l'étape consistant à :
) empêch r le tube de bande de subir un raccourcissement longitudinal pendant que ledit tube subit le rétrécissement radial de l'étape b.

33. Procédé selon la revendication 32 dans lequel l'étape c comprend également :
le positionnement de façon coaxiale d'une greffe de base tubulaire à paroi mince possédant une épaisseur dans l'intervalle de 0,15 à 0,65 mm dans ledit tube de bande.

34. Procédé selon la revendication 32 dans lequel l'étape c comprend également :
le positionnement de façon coaxiale d'une greffe de base tubulaire à paroi ultra-mince possédant une épaisseur inférieure à 0,15 mm dans ledit tube de bande.

35. Procédé selon la revendication 31 dans lequel la bande utilisée dans l'étape a est formée de PTFE expansé et fritté.

36. Procédé selon la revendication 31 dans lequel la greffe de base tubulaire utilisée dans l'étape c est formée de PTFE expansé et fritté.

37. Procédé de fabrication d'une greffe vasculaire tubulaire radialement extensible et renforcée par bande, ledit procédé comprenant les étapes consistant à :

a) fournir une quantité de bande de fluoropolymère expansé et fritté ;
b) rétrécir ladite bande de fluoropolymère expansé et fritté ;
c) fournir une greffe de base tubulaire formée de fluoropolymère expansé et ladite greffe de base tubulaire comprenant une lumière et une surface extérieure ;
d) enrouler la bande de fluoropolymère expansé et fritté, rétrécie sur la surface extérieure de ladite greffe de base tubulaire ;
e) conduire ladite bande à devenir fixée à la surface extérieure de ladite greffe de base tubulaire, de façon à former ladite greffe vasculaire tubulaire radialement extensible et renforcée par bande.

38. Procédé selon la revendication 37 dans lequel l'étape c comprend également :
la fourniture d'une greffe de base tubulaire à paroi mince possédant une épaisseur dans l'intervalle de 0,15 à 0,65 mm.

39. Procédé selon la revendication 37 dans lequel l'étape c comprend également :
la fourniture d'une greffe de base tubulaire à paroi ultra-mince possédant une épaisseur inférieure à 0,15 mm.

40. Procédé selon la revendication 37 dans lequel la bande fournie dans l'étape a est formée de PTFE expansé et fritté.

41. Procédé selon la revendication 37 dans lequel la greffe de base tubulaire fournie dans l'étape c est formée de PTFE expansé et fritté.

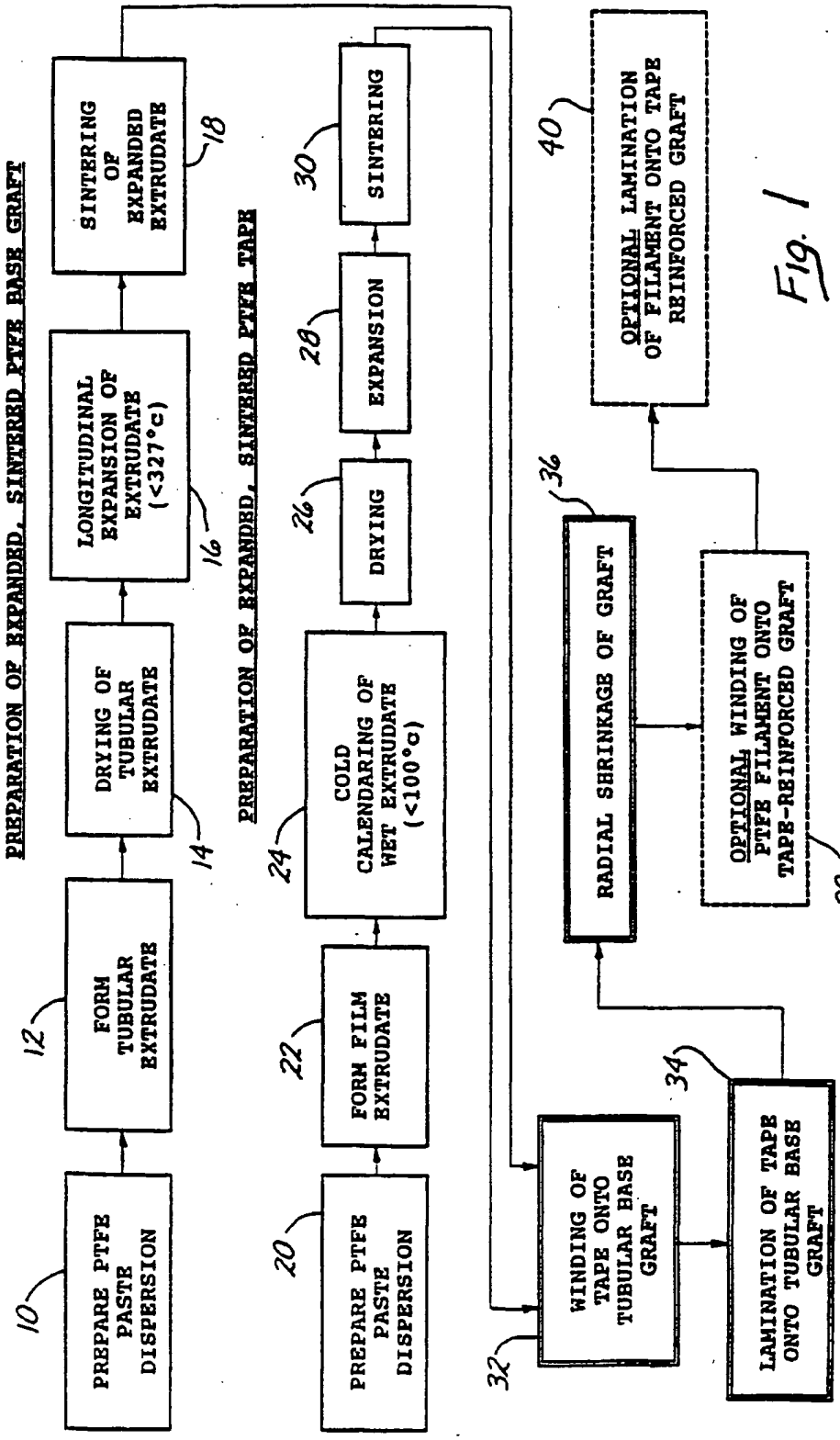
PREPARATION OF EXPANDED, SINTERED PTFE BASE GRAFT
PREPARE PTFE PASTE DISPERSION
10
FORM TUBULAR EXTRUDATE
12
DRYING OF TUBULAR EXTRUDATE
14
LONGITUDINAL EXPANSION OF EXTRUDATE (<327°C)
16
SINTERING OF EXPANDED EXTRUDATE
18
PREPARATION OF EXPANDED, SINTERED PTFE TAPE
PREPARE PTFE PASTE DISPERSION
20
FORM FILM EXTRUDATE
22
COLD CALENDARING OF WET EXTRUDATE (<100°C)
24
DRYING
26
EXPANSION
28
SINTERING
30
WINDING OF TAPE ONTO TUBULAR BASE GRAFT
32
LAMINATION OF TAPE ONTO TUBULAR BASE GRAFT
34
RADIAL SHRINKAGE OF GRAFT
36
OPTIONAL WINDING OF PTFE FILAMENT ONTO TAPE-REINFORCED GRAFT
38
OPTIONAL LAMINATION OF FILAMENT ONTO TAPE REINFORCED GRAFT
40

Fig. 1

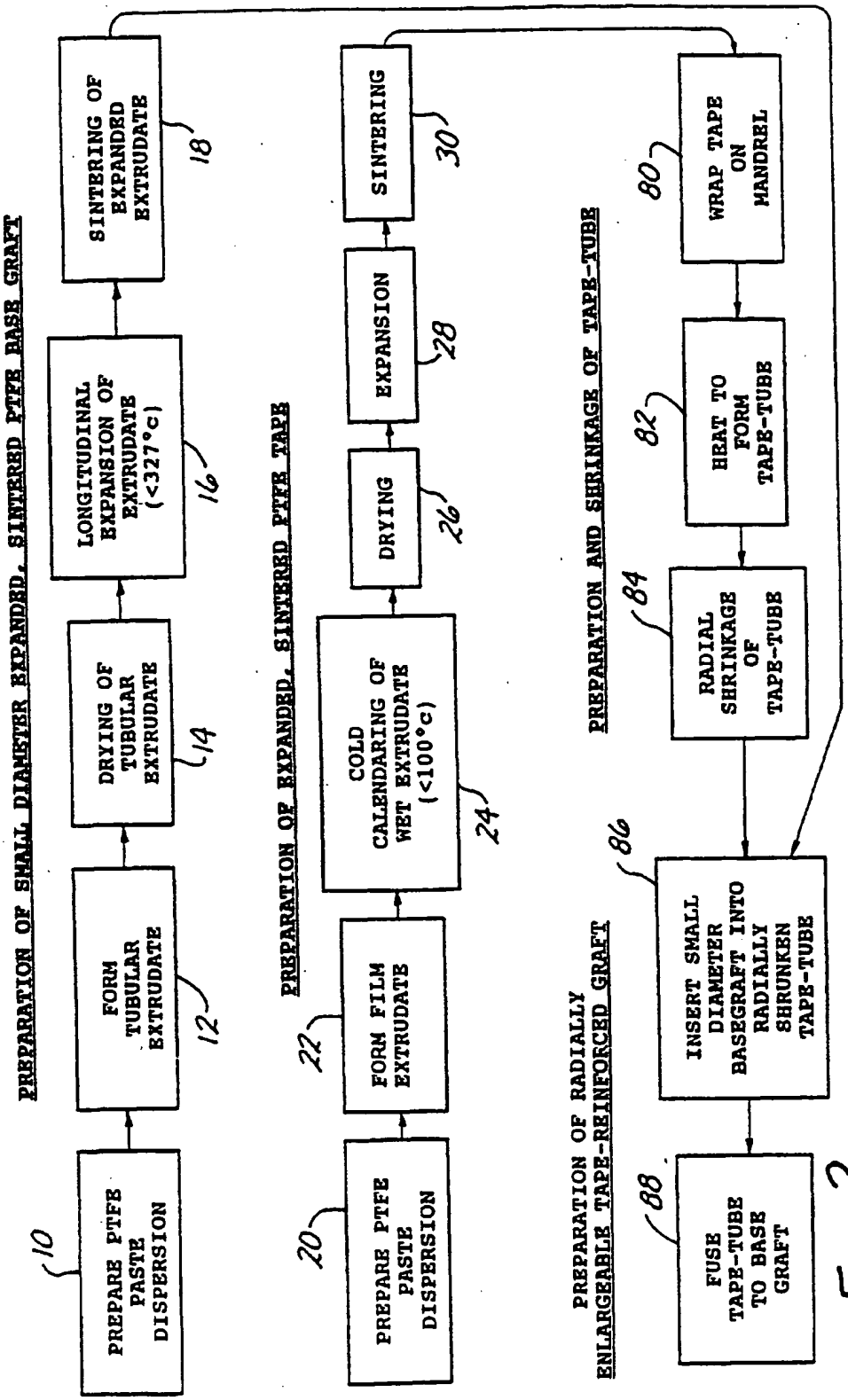
PREPARATION OF SMALL DIAMETER EXPANDED, SINTERED PTFE BASE GRAFT
PREPARE PTFE PASTE DISPERSION
10
FORM TUBULAR EXTRUDATE
12
DRYING OF TUBULAR EXTRUDATE
14
LONGITUDINAL EXPANSION OF EXTRUDATE (<327°c)
16
SINTERING OF EXPANDED EXTRUDATE
18
PREPARATION OF EXPANDED, SINTERED PTFE TAPE
PREPARE PTFE PASTE DISPERSION
20
FORM FILM EXTRUDATE
22
COLD CALENDARING OF WET EXTRUDATE (<100°c)
24
DRYING
26
EXPANSION
28
SINTERING
30
PREPARATION OF RADIALLY ENLARGEABLE TAPE-REINFORCED GRAFT
PREPARATION AND SHRINKAGE OF TAPE-TUBE
WRAP TAPE ON MANDREL
80
HEAT TO FORM TAPE-TUBE
82
RADIAL SHRINKAGE OF TAPE-TUBE
84
INSERT SMALL DIAMETER BASEGRAFT INTO RADIALLY SHRUNKEN TAPE-TUBE
86
FUSE TAPE-TUBE TO BASE GRAFT
88

Fig. 2